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5. 510(K) SUMMARY

Date Prepared:	August 25, 2010
Trade Name:	Funnel Guide Catheter™
Common Name:	Percutaneous Catheter
Classification:	Class II, 21 CFR 870.1250, Product Code DQY
Applicant:	Lazarus Effect, Inc. 560 Division Street Campbell, CA 95008 USA Telephone: (408) 409-2455 Fax: (408) 608-1999
Contact Person:	Carrie Neuberger Vice-President, Regulatory and Clinical Affairs and Quality Assurance
Predicate Devices:	Neuron Intracranial Access System, manufactured by Penumbra, Inc. Envoy Guiding Catheter, manufactured by Cordis Corporation

Device Description:

The Lazarus Effect Funnel Guide Catheter™ (Funnel Guide Catheter™) is a single-lumen, variable-stiffness catheter with an atraumatic nitinol wire braided funnel distal tip to facilitate the passage of other interventional and/or diagnostic devices. Device dimensions and configuration are shown on the product label. The Funnel Guide Catheter™ is compatible with introducer sheaths and guide catheters having an inner diameter of 6F or greater. A rotating hemostasis valve with side-arm adapter and a compatible guidewire may be used, but are not provided with the Funnel Guide Catheter™.

Intended Use:

The Funnel Guide Catheter™ is indicated for use in the peripheral and coronary vasculature for the introduction of interventional and/or diagnostic devices. The indicated use is substantially equivalent to that of the legally marketed predicate devices.

Technological Characteristics of the Device Compared to the Predicate Devices:

The Funnel Guide Catheter™ is intended for use in interventional radiological procedures. It is substantially equivalent to other interventional radiological devices currently on the market. The Funnel Guide Catheter™ is substantially equivalent to the identified predicate devices with regard to device design, materials, patient population and anatomical site. The intended use for the Funnel Guide Catheter has been revised and is a subset of the intended use for the predicate devices. This change, and any differences due to the technological characteristics of the Funnel Guide Catheter™ compared to its predicate devices do not raise new issues of safety or effectiveness.

Device	***Lazarus Effect Funnel Guide Catheter™ (Subject Device)***	***Penumbra Inc., Neuron Intracranial Access System***	***Cordis Endovascular Systems ENVOY Guiding Catheter***
Intended Use	The Funnel Guide Catheter™ is indicated for use in the peripheral and coronary vasculature for the introduction of interventional and/or diagnostic devices.	The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Envoy Guiding Catheter is intended for use in the peripheral, coronary, and neurovasculature for the introduction of interventional / diagnostic devices.
Design:			
Outer Diameter (OD)	6 French	6 French	6 French
Inside Diameter (ID)	0.062in	0.070in and 0.053in	0.070in
Working Length	102cm	95-115cm	90-100cm
Catheter shaft	Transition in stiffness from hub to tip	Transition in stiffness from hub to tip	Transition in stiffness from hub to tip
Wire Compatibility	0.035in/.038in	0.035in/.038in	0.035in/.038in
Materials	Predominantly PTFE, Stainless Steel, platinum, Pebax, Nitinol	Stainless Steel, platinum, hydrophilic coating	Predominantly PTFE, Stainless Steel, Nylon/polyurethane

Note: Materials in the predicate devices are not known with certainty. Material equivalence is demonstrated by performance tests and biocompatibility tests.

Summary of Studies:

Bench testing, biocompatibility testing and *in vivo* testing in the animal model were performed on the device materials and on finished devices. These tests included:

Bench Testing:

- Dimensional measurement
- Visual examination
- Fluoroscopic evaluation
- Kink resistance
- Simulated use
- Torque transmission
- Repeated use
- Navigation and insertion force
- Air and fluid leak
- Corrosion resistance
- Tensile testing (force at break)
- Fluid flow rate
- Burst pressure
- Product and packaging stability (shelf-life)
- Packaging integrity (seal strength and puncture resistance)

Biocompatibility Testing:

- Cytotoxicity
- Sensitization assay
- Intracutaneous reactivity
- Pyrogen
- Systemic toxicity
- Hemolysis
- Thromboresistance
- Complement Activation
- Sterilization

In-vivo Testing:

- Simulated use porcine model (including histology and fluoroscopic visibility)

The results of the performance, biocompatibility, and *in-vivo* tests verified that the Funnel Guide Catheter™ performs as designed and is suitable for its intended use.

Conclusion:

The data contained in this submission demonstrate that the Lazarus Effect Funnel Guide Catheter™ is substantially equivalent to the identified predicate devices in regards to device design, materials, patient population, anatomical site, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 12 2012

Lazarus Effect, Inc.
c/o Ms. Carrie Neuberger
Vice President, Regulatory and Clinical Affairs and Quality Assurance
560 Division Street
Campbell, CA 95008

Re: K102439
Trade/Device Name: Funnel Guide Catheter™
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 29, 2011
Received: November 30, 2011

Dear Ms. Neuberger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K102439

Device Name: Lazarus Effect - Funnel Guide Catheter™

Indications for Use:

The Funnel Guide Catheter™ is indicated for use in the peripheral and coronary vasculature for the introduction of interventional and/or diagnostic devices.

Prescription Use __X____ AND/OR Over-the-Counter Use

_____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102439